

In re Application of: Gila MAOR  
Serial No.: 10/627,739  
Filed: July 28, 2003  
Office Action Mailing Date: February 24, 2009

Examiner: Barnhart, Lora Elizabeth  
Group Art Unit: 1651  
Attorney Docket: 26243

### **REMARKS**

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1-5, 7, 9, 11-103 and 108 and 11-106 and 108 are in this Application. Claims 12, 13, 15, 16 and 24-103 were withdrawn from consideration. Claims 1-5, 7, 9, 11, 14, 17-23 and 108 have been rejected under 35 U.S.C. § 112 first and second paragraphs. Claims 7, 9 and 23 have now been canceled. Claims 1 and 20 have been amended herewith.

In a telephone interview graciously granted by the Examiner, Applicant discussed proposed amendments in an attempt to overcome the 35 U.S.C. § 112 first and second paragraphs rejections.

#### ***35 U.S.C. § 112, First Paragraph, Rejections***

The Examiner has rejected claims 1-9, 11, 14, 17-23 and 108 under 35 U.S.C. 112, first paragraph, because while the specification, while being enabling for a method of generating cultured chondrocytes that express type II collagen but not type I collagen by using one specific set of culture conditions, does not reasonably provide enablement for doing so using any given and culture conditions.

Specifically, the Examiner states that the as-filed specification includes a single working example in which mandibular condyles from neonatal tissue are harvested and the resulting cells are cultured in a culture medium (DMEM) supplemented with serum and ascorbic acid,  $\beta$ -glycerophosphate, calcium chloride and pyruvate and that culturing should be effected for at least 7 days.

The Examiner further states that the art is unpredictable and cites the arts of Cheung et al. 4,757,017 and Schnabel et al. 2002, Osteoarthritis and Cartilage 10:62-70) as support for this statement.

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The Examiner further states that the arguments regarding the importance of the source of the chondrocytes are unsupported by evidence or declarations.

Examiner's rejections are respectfully traversed. Claim 1 has now been amended. Claim 23 has been cancelled herewith.

In order to expedite prosecution Applicant has elected to amend claim 1, such that it is clear that the cells are isolated from a neonatal mammalian mandibular tissue and cultured in the presence of a culture medium supplemented with serum,  $\beta$ -glycerolphosphate, pyruvate, calcium chloride and ascorbic acid. Clearly, this amendment is supported by now cancelled claim 23, Example 1 of the instant specification (page 44 lines 9-23) and pages 27-28. In view of the above added limitations, it is Applicant's position that the rejection over 112 first paragraph enablement should be withdrawn.

The Examiner further rejected claims 7 and 9 under 35 U.S.C., 112, first paragraph, as failing to comply with the written description requirement. In order to expedite prosecution, claims 7 and 9 have been cancelled without prejudice, thereby rendering moot Examiner's rejection in this case.

The Examiner rejected claims 20 and 23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject which Applicant regards as the invention. Specifically, the Examiner states that claim 20 does not properly limit claim 1.

Applicant thanks the Examiner for pointing out this error. Accordingly, claim 20 has been amended to properly depend from claim 1. Support for the amendment can be found in page 31 line 24.

The Examiner rejected claim 23 since it requires that the tissue is "derived from a neonatal mammal". Examiner's rejection is respectfully traversed. Claim 23 has been cancelled without prejudice, rendering moot Examiner's rejection in this case.

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The Examiner further rejected claims 1-5, 7, 9, 11, 14, 17-23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject which Applicant regards as the invention.

Specifically, the Examiner states that the claims lack an essential element, that is, the age of the donor whose cartilage tissue provides the chondrocytes.

While traversing Examiner's rejection, Claim 1 has been amended herewith, such that it is clear that the cells are isolated from a mandibular tissue of a neonatal mammal.

In view of the above amendments and remarks it is respectfully submitted that claims 1-5, 11, 14, 17-22 and 108 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Martin D. Moynihan".

Martin D. Moynihan  
Registration No. 40,338

Date: May 18, 2009